

S/N 10/639,949

PATENT


IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

|                   |   |                 |             |
|-------------------|---|-----------------|-------------|
| Applicant:        | SETHI ET AL.  | Examiner:       | D. JONES    |
| Serial No.:       | 10/639,949  | Group Art Unit: | 1614        |
| Filed:            | AUGUST 12, 2003                                     | Docket No.:     | 12695.6USD5 |
| Confirmation No.: | 6992  | Customer No.:   | 23552       |
| Title:            | TREATMENT OF CARDIOVASCULAR AND RELATED PATHOLOGIES |                 |             |

CERTIFICATE UNDER 37 CFR 1.10:

"Express Mail" mailing label number: EV 639593460 US  
Date of Deposit: March 23, 2006

I hereby certify that this paper or fee is being deposited with the U.S. Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

By:   
Name: Sheryl A. Boerboom

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (37 C.F.R. § 1.97(c))**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Dear Sir:

With regard to the above-identified application, the items of information listed on the enclosed Form 1449 are brought to the attention of the Examiner.

This statement should be considered because it is submitted after the mailing date of a first Office Action on-the-merits or a first Office Action after filing a Request for Continued Examination under 37 C.F.R. § 1.114 or a CPA under 37 C.F.R. § 1.53(d), but before the mailing date of: i) a final action under 37 C.F.R. § 1.113; ii) a Notice of Allowance under 37 C.F.R. § 1.311; or iii) an action that otherwise closes prosecution on the application. Please charge Deposit Account No. 13-2725 for consideration of the items listed on the enclosed Form 1449.

In accordance with 37 C.F.R. § 1.98(a)(2), a copy of each document or other information listed on the enclosed Form 1449 is provided.

No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102 and 103 and Applicants reserve the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to establish that the reference(s) are not "prior art." Moreover, Applicants do not represent that a reference has been thoroughly reviewed or that any relevance of any portion of a reference is intended.

Consideration of the items listed is respectfully requested. Pursuant to the provisions of M.P.E.P. 609, it is requested that the Examiner return a copy of the attached Form 1449, marked as being considered and initialed by the Examiner, to the undersigned with the next official communication.

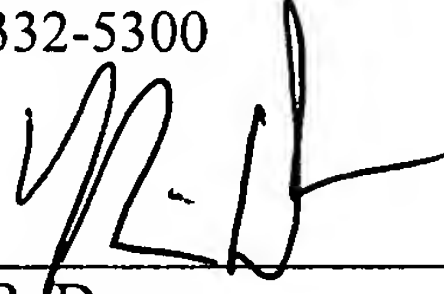
Please charge any additional fees or credit any overpayment to Deposit Account No. 13-2725.

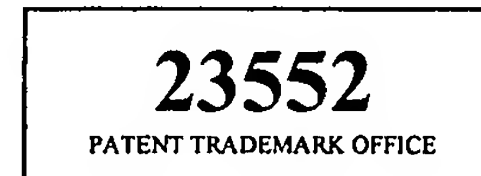
Respectfully submitted,

MERCHANT & GOULD P.C.  
P.O. Box 2903  
Minneapolis, Minnesota 55402-0903  
(612) 332-5300

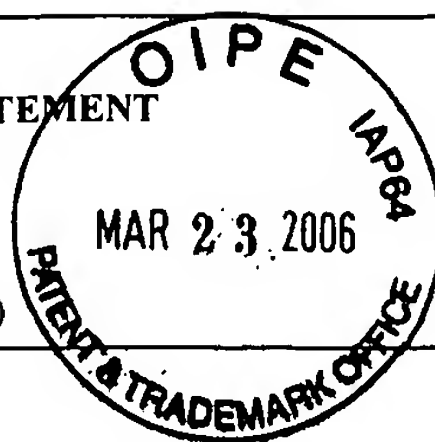
Date: \_\_\_\_\_

March 23, 2006

  
\_\_\_\_\_  
Brian R. Dorn  
Reg. No. 57,395



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| <b>FORM 1449*</b><br><b>INFORMATION DISCLOSURE STATEMENT</b><br><br><b>IN AN APPLICATION</b><br><br>(Use several sheets if necessary) | <b>DOCKET NUMBER:</b><br>12695.6USD5 | <b>APPLICATION NUMBER:</b><br>10/639,949 |
|   | <b>APPLICANT:</b> SETHI ET AL.       |  |
|   | <b>FILING DATE:</b> August 12, 2003  | <b>GROUP ART UNIT:</b> 1614              |



| U.S. PATENT DOCUMENTS |              |      |      |       |          |                               |  |
|-----------------------|--------------|------|------|-------|----------|-------------------------------|--|
| EXAMINER<br>INITIAL   | DOCUMENT NO. | DATE | NAME | CLASS | SUBCLASS | FILING DATE<br>IF APPROPRIATE |  |
|                       |              |      |      |       |          |                               |  |
|                       |              |      |      |       |          |                               |  |

| FOREIGN PATENT DOCUMENTS |              |      |         |       |          |             |    |
|--------------------------|--------------|------|---------|-------|----------|-------------|----|
|                          | DOCUMENT NO. | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION |    |
|                          |              |      |         |       |          | YES         | NO |
|                          |              |      |         |       |          |             |    |

| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) |  |  |
|--|--|--|
|  |  | "Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline" A Report on the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes and its Panel on Folate, Other B Vitamins, and Choline and Subcommittee on Upper Reference Levels of Nutrients, Food and Nutrition Board, Institute of Medicine (1998) (ISBN 0-309-06554-2) |
|  |  | Bässler, "Megavitamin Therapy with Pyridoxine", <i>Internat. J. Vit. Nutr. Res.</i> 58: 105-118 (1988)   |
|  |  | Chumnantana et al., "Vitamin B <sub>6</sub> compounds prevent the death of yeast cells due to menadione, a reactive oxygen generator", <i>Biochimica et Biophysica Acta</i> 1722:84-91 (2005)  |
|  |  | Higuchi et al. "Aminophospholipid glycation and its inhibitor screening system: A new role of pyridoxal 5'-phosphate and pyridoxal as lipid glycation inhibitor", <i>J Lipid Res.</i> 2006 Feb 9; doi:10.1194/jlr.M500348-JLR200.  |
|  |  | Hirai et al., "Cerebrospinal fluid somatostatin in West syndrome: changes in response to combined treatment with high-dose pyridoxal phosphate and low-dose corticotropin", <i>Neuropeptides</i> 32(6):581-586 (1998)  |
|  |  | Holman, "Pyridoxine - Vitamin B-6", <i>J. Austral. Coll. Nutr. Environ. Med.</i> 14: 5-16 (1995)   |
|  |  | Kannan et al., "Effect of Vitamin B6 on oxygen radicals, mitochondrial membrane potential, and lipid peroxidation in H2O2-treated U937 monocytes", <i>Free Radical Biol. Med.</i> 36: 423-428 (2004).  |
|  |  | Kuo et al. "Pyridoxal phosphate-responsive epilepsy with resistance to pyridoxine", <i>Pediatr. Neurol.</i> 26: 146-147 (2002)   |
|  |  | Ohtsuka et al., "Treatment of the West Syndrome with High-Dose Pyridoxal Phosphate", <i>Brain &amp; Development</i> 9(4):418-421 (1987)  |
|  |  | Schaumberg et al., "Sensory neuropathy from pyridoxine abuse", <i>N. Eng. Med. J.</i> 309: 445-448 (1983)  |
|  |  | Seki, "Combination Treatment of High-Dose Pyridoxal Phosphate and Low-Dose ACTH in Children with West Syndrome and Related Disorders", <i>The Japanese Journal of Psychiatry and Neurology</i> 44(2):219-237 (1990)  |
|  |  | Ubbink et al., "Effect of different levels of oral pyridoxine supplementation on plasma pyridoxal-5'-phosphate and pyridoxal levels and urinary vitamin B-6 excretion," <i>Am. J. Clin. Nutr.</i> 46: 78-85 (1987)   |
|  |  | Wang et al., "Pyridoxal phosphate is better than pyridoxine for controlling idiopathic intractable epilepsy" <i>Arch. Dis. Child.</i> 90: 512-515 (2005)   |

**23552**

PATENT TRADEMARK OFFICE

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|---|------------------------|
| <b>EXAMINER</b>   | <b>DATE CONSIDERED</b> |
| EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant. |                        |